

Remarks

Claims 1-78 are pending in the application. Claims 1-24, 26, 27, 29-33, 37-40, 45-70, and 72-78 stand rejected, and claims 25, 28, 34-36, 41-44, and 71 have been withdrawn from consideration. No claims have been amended, added, or canceled. Applicant respectfully requests reexamination and reconsideration of the case in light of the following remarks. Each of the rejections levied in the Office Action is addressed individually below.

I. Rejection under 35 U.S.C. § 102(b) or § 103, in view of Grinstaff *et al.*, U.S. Patent 5,639,473. Claims 1-24, 26, 29, 30-33, 37, 39-40, 45, 46, 47, 49-62, 65-70, and 73-78 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Grinstaff *et al.* (U.S. Patent 5,639,473), or alternatively, under 35 U.S.C. § 103 as being unpatentable over Grinstaff *et al.* (U.S. Patent 5,639,473). The Examiner maintains that Grinstaff *et al.* teach the making of microparticles with a matrix consisting of two components selected from lipids, proteins, and sugar. This, however, overstates what Grinstaff *et al.* disclose. Grinstaff *et al.*, in fact, disclose microparticles with a matrix of biocompatible material which can be cross-linked. For example, in column 8, lines 34-53, Grinstaff *et al.* disclose that materials bearing sulfhydryl groups, disulfide groups, or precursors of esters, amides, ethers, and the like can be used in forming microparticles. The materials used must undergo cross-linking during ultrasonic irradiation to be useful in the invention of Grinstaff *et al.*

Grinstaff *et al.* do not teach a combination of at least two components of the matrix selected from the group consisting on lipids, proteins, sugar, and synthetic polymers. Instead, Grinstaff *et al.* just rely on using one type of biocompatible material suitable for cross-linking in preparing the microparticles. Without this combination of at least two components as claimed in independent claims 1-6, Grinstaff *et al.* cannot anticipate or render obvious the claimed invention. With respect to claims 1 and 2 which recite three components, Grinstaff *et al.* clearly fails to teach the claimed invention.

In addition, the present invention includes no limitation that the materials of the matrix be suitable for cross-linking upon ultrasonic irradiation or that they have sulfhydryl groups for disulfide formation. Instead, the matrix of the microparticles of the present invention which includes at least two components selected from lipids, proteins, sugars, and synthetic polymers

does not require cross-linking in order to form microparticles. Since Grinstaff *et al.* do not disclose such particles without the need for suitable functional groups for cross-linking, Grinstaff *et al.* cannot anticipate or render obvious the claimed invention.

In summary, Grinstaff *et al.* do not teach the use of at least two components selected from the group consisting of proteins, lipids, sugars, and synthetic polymers, and Grinstaff *et al.* only teach the use of materials suitable for cross-linking in the preparation of microparticles. Given these differences between Grinstaff *et al.* and the claimed invention, Applicant submits that Grinstaff *et al.* does not anticipate or render obvious the claimed invention. Applicant respectfully requests that the rejection be removed.

II. Rejection under 35 U.S.C. § 102(a), 102(e) or 103(a), in view of Edwards *et al.*, U.S. Patent 5,985,309. Claims 1-24, 26, 27, 29-33, 37-40, 45-69, and 73-78 have been rejected under 35 U.S.C. § 102(a) or 102(e) as being anticipated by Edwards *et al.* (U.S. Patent 5,985,309), or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Edwards *et al.* (U.S. Patent 5,985,309). In order to remove the '309 patent from consideration by the Examiner, Applicant has submitted a Declaration under 37 C.F.R. § 1.132 by Robert S. Langer stating that the claimed invention was not invented by another. Applicant requests that the rejection be removed since the material disclosed in the '309 patent was not invented by another and, therefore, does not anticipate or render obvious the claimed invention in the present application.


III. Rejection under 35 U.S.C. § 103(a), as being unpatentable over Grinstaff *et al.*, U.S. Patent 5,639,473, in view of Wheeler *et al.*, U.S. Patent 5,976,567. Claims 1-24, 26, 27, 29-33, 37-40, 45-70, and 72-78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Grinstaff *et al.* (U.S. Patent 5,639,473) in view of Wheeler *et al.* (U.S. Patent 5,976,567). In addition to the teaching of Grinstaff *et al.*, the Examiner cites Wheeler *et al.* for the proposition that DPPC can be used as the lipid in the inventive microparticles. However, even if Wheeler *et al.* do teach that DPPC can be used as the lipid in the inventive particles to enhance the transfection of nucleic acids, Wheeler *et al.* do not overcome the deficiencies in the teachings of Grinstaff *et al.* as described above. For example, even when combined with Grinstaff *et al.*, Wheeler *et al.* do not teach that at least two or at least three components of the group consisting

of lipids, proteins, sugars, and synthetic polymers are useful in the preparation of microparticles nor does Wheeler *et al.* teach that components without functionalities for cross-linking are useful in preparing the inventive particles. Therefore, Applicant submits that the combination of Wheeler *et al.* and Grinstaff *et al.* fails to render obvious the claimed invention given the differences between the combination and the claimed invention.

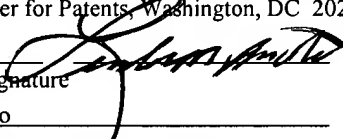
In view of the forgoing amendments and arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,


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